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Original article

# Clinical effectiveness and safety of a distraction-rotation knee brace for medial knee osteoarthritis

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ABSTRACT

*Objective:* Evaluation of the clinical effectiveness and safety of a new custom-made valgus knee brace (OdrA) in medial knee osteoarthritis (OA) in terms of pain and secondary symptoms.
*Methods:* Open-label prospective study of patients with symptomatic medial knee OA with clinical evaluation at 6 and 52 weeks (W6, W52). We systematically assessed pain on a visual analog scale (VAS), Knee injury and Osteoarthritis Outcome Score (KOOS), spatio-temporal gait variables, use of nonsteroidal anti-inflammatory drugs (NSAIDs) and analgesic-sparing effects of the brace and tolerance. Mean scores were compared at baseline, W6 and W52 and the effect size (ES) and 95% confidence intervals (95% CIs) were calculated.
*Results:* We included 20 patients with knee OA (mean age 64.2 ± 10.2 years, mean body mass index 27.2 ± 5.4 kg/m$^2$). VAS pain and KOOS were improved at W6 and W52: pain (ES = 0.9 at 1 year), amelioration of other symptoms (ES = 0.4), and function in activities of daily living (ES = 1.1), sports and leisure (ES = 1.5), quality of life (ES = 0.9) and gait speed (ES = 0.41). In total, 76% of patients showed clinical improvement at 1 year. Analgesic and NSAIDs consumption was significantly decreased at W6 and W52. One serious adverse effect noted was lower-limb varices, and observance was deemed satisfactory at 1 year.
*Conclusion:* This new unloader brace appeared to have good effect on medial knee OA, with an acceptable safety profile and good patient compliance.



## 1. Introduction

Knee osteoarthritis (OA) is a chronic disabling joint disease that causes increasingly severe functional impairment in everyday activities. The medial compartment is the most frequently affected, given the physiological high loading on this zone. The condition is frequently aggravated by constitutional or acquired bow-leggedness [1,2]. To limit pain in medial-compartment knee OA, conservative medical management combining pharmacological and nonpharmacological treatment is recommended [3–5]. The use of medical devices such as foot pronation orthotics [6,7] or articulated valgus knee braces is advocated [8–10]. Although the beneficial effect of these devices on symptoms are related to their proprioceptive properties [11,12] or muscle activation [13–15], the principal effect stems from their ability to unload the medial compartment, where the pain originates [1,2,8,16–18].

The improvement in functional capacities is better with unloader knee braces than knee sleeves or neutral articulated braces [8,16,19,20]. However, the efficacy of the braces is still debated [10,21,22], and tolerance to the braces is poor because they irritate the skin, impair venous return, can cause oedema and are bulky, which can hamper certain movements in everyday life [23]. In clinical practice, this type of orthotic device is rarely prescribed by physicians specialized in degenerative joint diseases of the knee because they prefer pharmacological treatments and/or rehabilitation [8].

Recently, the PROTEOR group developed a new custom-made brace, the OdrA system (Fig. 1). The brace features an innovative system to unload the medial compartment by distraction and

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**Fig. 1.** Knee brace with the OdrA system (PROTEOR, France).

external rotation. This mechanism allows for shifting the vertical axis of the ground reaction force vector backwards and medially toward the center of the knee joint, which reduces the knee adduction moment during the propulsion phase but disappears in the swing phase or at rest, with the knee bent. The new system, which was recently validated biomechanically in terms of kinetic and kinematic dimensions [24], is also less cumbersome because it is custom-made, with few voluminous tibial and femoral straps. This dynamic unloader brace, with no effect at rest with the knee bent, is equipped with a rack and pinion system that plays a dual role in weight-bearing positions: distraction and external rotation of the leg. The effect is to shift the centre of the load toward the natural inter-condyle position and thus to limit overloading of the medial compartment [24], which is often aggravated in patients with bow-leggedness or with medial meniscus degeneration.

In terms of the current overall re-evaluation of treatments in knee OA, the beneficial effects of this device on symptoms by unloading the medial compartment as well as tolerance and compliance could lead to its use in clinical practice. However, in addition to data needed from validated algo-functional questionnaires, spatio-temporal gait data are needed to provide an objective evaluation of the functional benefits of this dynamic knee brace on gait [18,25,26]. These investigations are in response to recent requests from accreditation organisations responsible for authorising the commercialisation of these medical devices: the French health authority requires a high level of scientific evidence for these orthotic devices, with high-quality therapeutic trials, on which marketing approval for these expensive and not risk-free devices depends [27].

The primary objective of this interventional prospective single-centre study was to evaluate the efficacy of the new valgus knee brace with the OdrA system for medial-compartment knee OA on pain at week 6 (W6). Secondary objectives were to evaluate the effect of the brace on other symptoms in the short-term (W6) and medium-term (W52) and to provide data on tolerance and compliance in clinical practice.

## 2. Materials and methods

### 2.1. Patients

Patients consulting at the Department of Rheumatology and Physical Medicine of Dijon University Hospital over six months were recruited consecutively. We included patients 40 to 80 years old who had unilateral medial-compartment knee OA according to ACR criteria [28] (medial compartment pain at rest $>$ 4 on a 0–10 visual analog scale [VAS]), radiological stage II, III or IV according to the Kellgren and Lawrence classification [29] determined by radiography performed in the previous six months, with no change in pharmacological treatment in the previous six months and no injections of hyaluronic acid or corticosteroids during this period. Exclusion criteria were presence of a disease that could interfere with gait analysis or inflammatory or rapidly destructive knee OA. Patients with an indication for surgery according to the medical specialist consulted, a valgus morphotype or another disease likely to cause knee pain or modify gait were also excluded. After inclusion and custom-moulding of the OdrA brace, patients were instructed to wear the brace for at least 6 h/day, 5 days/week.

The study was conducted in accordance with good clinical practices and the Declaration of Helsinki (ClinicalTrials.gov identifier: NCT01884883) and was approved by the local ethics committee. Patients gave informed consent to be in the trial.

### 2.2. Gait protocol

At inclusion and at W6 after wearing the brace, patients underwent a standard protocol for quantified gait analysis (VICON system, Oxford, UK). This gait protocol has been described elsewhere for the biomechanical validation of the OdrA device [24]. Briefly, reflective markers, detected by eight infrared cameras, were placed on the pelvis and lower limbs of patients, who were instructed to walk up and down a 10-m path 12 times. The spatio-temporal gait variables were recorded over the 6 m in the middle of the track to avoid acceleration and deceleration phenomena. The patients were told to walk at their usual comfortable speed.

### 2.3. Data collection

At inclusion, the following clinical data were collected: age, sex, body mass index (kg/m$^2$), disease duration, and radiological stage by the Kellgren and Lawrence classification [29].

Judgement criteria were collected at inclusion and at 6 and 52 weeks (W6, W52). For the principal outcome criteria (improvement in pain at W6 compared with inclusion), pain was measured at rest by a VAS (0–100).

The following secondary outcomes were evaluated. Improvement in pain at W52 compared with at inclusion was measured at rest by a VAS (0–100). Overall self-evaluation of disease severity was measured by a VAS (0–100). Function was measured by the Knee injury and Osteoarthritis Outcome Score (KOOS) consisting of 42 questions covering 5 domains, each scored from 0 (worst) to 100 (best) [30]: pain, other symptoms, function in activities of daily living (ADL), function in sports and leisure (SL) activities and quality of life (QoL). This internationally validated score includes all of the domains of Western Ontario and McMaster Universities Arthritis Index (WOMAC; pain, stiffness, function) and adds more demanding activities and important aspects of QoL. The KOOS can be represented in the form of a graph, with a line linking the different domains [31]. Consumption of nonsteroidal anti-inflammatory drugs (NSAIDs) and analgesics was evaluated by the number of days per week each class of drug was taken. Disease severity at W6 and W52 was measured by a semi-quantitative

Likert scale: 1, severely worsened; 2, worsened; 3, stable; 4, improved; 5, much improved. Tolerance to the brace and compliance was evaluated by recording adverse effects in a patient diary and by mean time the brace was worn (number of hours per day and number of days per week). The following spatio-temporal gait variables were collected at W0 and W6 [24]: walking speed (m/s), stride length (m), stride width (m), stride frequency (Hz), single and double support time (% of gait cycle) and step dephasing (% of gait cycle).

### 2.4. Statistical analysis

The principal analysis was intent-to-treat (ITT), with last observation carried forward (LOCF) used for missing data. Data are described with mean ± SD for clinical and gait spatio-temporal variables. Scores at different times were compared with those at inclusion by Wilcoxon matched pairs test. $P < 0.05$ was considered statistically significant. The amplitude of the therapeutic effect of the brace for each judgement criterion was evaluated by the effect size (ES) with the following interpretation: 0 to 0.5, weak effect; 0.5 to 0.8, moderate effect; > 0.8, major effect [32]. For ES values (clinical and spatio-temporal parameters), 95% confidence intervals (95% CIs) were calculated by the non-parametric bootstrap method.

According to data in the literature from similar clinical studies, improvement in pain on a VAS at W6 (principal criterion) should be at least 20%. With an alpha risk of 0.05 and power of 80%, a minimum of 15 subjects was necessary. Taking into account the possibility of patients leaving the trial, we needed to include 20 patients for 1 year of follow-up. Statistical analysis involved use of Statistica v10.2 (Statsoft Inc., Tulsa, USA).

## 3. Results

We included 20 patients in the study (16 females; mean age 64.2 ± 10.2 years; mean body mass index 27.2 ± 5.4 kg/m$^2$) (Table 1). Pain, disease severity and functional disability at inclusion were high, with no indication for surgery according to the treating rheumatologist. In total, 16 patients (80%) were taking level I or II analgesics and 6 (30%) NSAIDs. At W6, clinical and gait analysis data were analyzed for 19 patients because one patient had to stop wearing the brace due to venous intolerance and at W52, 18 of the 19 patients were re-evaluated (one patient lost to follow-up).

**Table 1**
Characteristics of the 20 patients wearing the OdrA brace for knee osteoarthritis (OA) at inclusion.

| Characteristics | |
|---|---|
| *Age (years)* | 64.2 ± 10.2 |
| *Sex ratio (F/M), no. of patients* | 16/4 |
| *BMI (kg/m$^2$)* | 27.2 ± 5.4 |
| *Disease duration (years)* | 6.4 ± 4.7 |
| *Pain, VAS (0–100)* | 63.1 ± 12.8 |
| *Disease severity, VAS (0–100)* | 64.2 ± 16.5 |
| *WOMAC function (0–100)* | 56.7 ± 12.8 |
| *Symptomatic treatments (% patients)* | |
| Analgesics | 80 |
| NSAIDs | 30 |
| SYSADOAs | 35 |
| *Radiographic stage of knee OA* | |
| *Kellgren and Lawrence classification, no. of patients* | |
| II | 5 |
| III | 9 |
| IV | 6 |

Data are mean ± SD unless indicated.
BMI: body mass index; VAS: visual analog scale; WOMAC: Western Ontario and McMaster University Osteoarthritis Index; NSAIDs: nonsteroidal anti-inflammatory drugs; SYSADOAs: symptomatic slow-acting drugs.

At W6, mean pain score had decreased by more than 50% from inclusion (63.1 ± 12.8 to 29.8 ± 14.2, $P < 0.001$) (Table 2; Fig. 1). The ES at W6 was 2.6 (95% CI 1.6–2.6); the mean pain score was 38.1 ± 17.4 at W52 (ES 2.1 [1.0–2.8]). A significant benefit was also seen for functional repercussions at W6 ($P < 0.01$, ES > 1), whatever the KOOS domain: pain (ES 1.9 [1.5–2.5]); other symptoms (ES 1.2 [0.4–2.0]); function ADL (ES 1.8 [1.4–2.2]); function SL (ES 1.7 [1.2–2.2]); and QoL (ES 1.1 [0.3–1.9]). At W52, this benefit on symptoms remained significant as compared with at inclusion for all domains (Fig. 2).

However, the domains of pain, symptoms and function ADL were significantly decreased between W6 and W52. At W6, 85% of patients thought that their state with regard to knee OA had "improved" or "much improved" as compared with 76% at W52.

The consumption of NSAIDs and analgesics had decreased significantly at W6 and W52 ($P < 0.05$). At W52, the consumption of analgesics had decreased to a mean of 1.3 days per week as compared with 4.5 at inclusion, and one third of patients had stopped analgesics completely. For NSAIDs, of the six patients who were taking these at least once a week, only one continued to take them regularly at W52. Concerning professional activities, for those who had not retired (40% of professionally active patients at inclusion), two of the three patients on sick leave because of knee OA were able to go back to work part- or full-time at W52.

Concerning the gait analysis (Table 3), between inclusion and W6, walking speed increased because of a concomitant increase in stride length and frequency. Walking speed had increased by a mean of 10% between inclusion and final evaluations (ES 0.41 [95% CI 0.06–0.75], $P < 0.05$) and exceeded 1 m/s, considered appropriate for people in this age group. Stride length increased to a lesser degree (ES 0.25 [0.09–0.51]). In contrast, stride width, step dephasing and single and double support time were not significantly modified by wearing the brace. The ES for objective gait variables (0.16–0.45) was smaller than that for subjective clinical parameters.

Concerning device tolerance, one female patient had to stop the study early because of aggravation of lower-limb varicose veins, although Doppler ultrasonography revealed no deep vein thrombosis. Six patients reported one or several superficial adverse effects concerning the skin: local heat ($n = 2$), moderate irritation ($n = 4$), and zone of excessive weight bearing at the front of the tibia ($n = 5$). The patients wore the knee brace for a mean of >8 h/day and > 6 days/week at W6, with a decrease to a mean of 6 h/day and 4.7 days/week at W52. Most patients reported no particular difficulties in putting on and taking off the brace, but some reported difficulties in getting dressed ($n = 5$) because of the lateral hinges.

## 4. Discussion

The results of this clinical evaluation of a new valgus knee brace, the OdrA, for which the biomechanical properties have already been validated [24], show that the brace effectively reduced symptoms of medial-compartment knee OA, in both the short-term (ES at W6 from 1.1 [95% CI 0.3–1.9] to 2.6 [1.6–2.6]) and the medium-term (ES at W52 from 0.9 [0.3–1.5] to 1.9 [1.0–2.8]) according to KOOS scores. These results are better than those reported in the literature (ES 0.2–0.7) for unloader braces used by other patients with symptomatic knee OA [16,26,33–35]. This improvement is superior to the minimal clinically important difference (MCID) reported for the KOOS (37). However, this threshold (MCID 9/100), which depends on patient characteristics, is recognized only for the KOOS QoL [36] and function in ADL [37] and is equivalent to the MCID for the WOMAC function subscale in knee OA [38].

**Table 2**
Clinical scores at inclusion (W0), 6 weeks (W6) and 1 year (W52) after wearing the OdrA knee brace and magnitude of the therapeutic effect (effect size).

| Clinical variables | W0 $n=20$ | W6 $n=19$ | W52 $n=18$ | ES (95% CI) | |
|---|---|---|---|---|---|
| | | | | W6 | W52 |
| *Pain, VAS (0–100)* | 63.1 ± 12.8 | 29.8 ± 14.2* | 38.1 ± 17.4*§ | 2.6 (1.6–3.6) | 1.9 (1.0–2.8) |
| *Disease severity, VAS (0-100)* | 64.2 ± 16.5 | 34.1 ± 16.8* | 36.9 ± 15.9*§ | 1.9 (1.1–2.7) | 1.7 (1.0–2.4) |
| *KOOS (0–100)* | | | | | |
| Pain | 42.6 ± 12.5 | 66.0 ± 13.6* | 54.3 ± 13.2*§ | 1.9 (1.4–2.4) | 0.9 (0.5–1.3) |
| Symptoms | 54.4 ± 17.3 | 75.7 ± 17.5* | 60.2 ± 16.2*§ | 1.2 (0.4–2.0) | 0.4 (0.05–0.9) |
| ADL | 44.5 ± 12.6 | 67.8 ± 11.9* | 58.5 ± 12.7*§ | 1.8 (1.4–2.2) | 1.1 (0.6–1.6) |
| SL | 14.5 ± 13.4 | 37.3 ± 12.9* | 34.0 ± 12.4* | 1.7 (1.2–2.2) | 1.5 (0.7–2.2) |
| QoL | 28.6 ± 17.4 | 45.9 ± 23.3* | 45.7 ± 16.5* | 1.0 (0.3–1.7) | 0.9 (0.3–1.5) |

Data are mean ± SD unless indicated.
KOOS: Knee injury and Osteoarthritis Outcome Score (0–100, 0, worst, to 100, best); ADL: activities of daily living; SL: sport and leisure activities; QoL: quality of life; ES: effect size; 95% CI: 95% confidence interval.
*$P < 0.05$ comparing W6 vs W0 and W52 vs W0.
§$P < 0.05$ comparing W6 vs W52.

Tolerance of the brace seemed to be good, except for one patient with lower-limb varicose veins, which may be a contraindication for this type of semi-rigid knee support. The brace seems to be relatively easy to use in everyday life, even in older patients, and thus has few of the constraints frequently reported with this type of apparatus concerning putting it on or the bulkiness [23].

Our study contains some limitations. The recruitment at a teaching hospital implies bias in the selection of patients with symptomatic knee OA. As well, the study had a small sample size, which could have hidden significant differences and did not allow us to identify predictors of a good response by multivariate analysis for defining the profile of patients. Therefore, the results need to be confirmed in larger studies. The possible placebo effect, which is well known in OA [39], also needs to be considered in this evaluation of benefits of the brace for symptoms. The results were still positive at one year and compliance was good, which suggests that the effect on symptoms was substantial; rates of pain relief with these medical devices often decrease quickly in the medium-term [40]. Only a randomised study comparing a neutral placebo brace could estimate the part of pain relief related to the placebo effect. A comparative randomised study comparing a reference articulated unloader knee brace already on the market could have been proposed to overcome this weakness, but such an analysis could not be realized in this preliminary study.

Pain and function were substantially improved with the brace, as shown by the ES (>0.8) and the high rate of satisfaction among patients (>75% at one year). The reduced consumption of drugs achieved by wearing the brace is important; this judgement criterion is rarely reported for these braces (one negative study for NSAIDs and analgesics and two positive studies [19,20,41]). This latter point is of clinical relevance for this disease, with disability implications for everyday life activities, and for OA patients, who are often older and taking a large number of drugs. Concerning the clinical follow-up at one year, two of the three patients on sick leave at inclusion were able to return to work and nine patients who had stopped physical activities (sport and/or leisure) were able to resume them. Wearing the brace was accompanied by improved QoL, as was previously reported with this type of apparatus [34], and underlines the importance of taking this pertinent judgement criterion into account. It also justifies choosing the KOOS rather than the Lequesne or WOMAC assessment, because this recently validated international score evaluates more demanding activities (running, squatting) and addresses interesting aspects of QoL [30]. In the literature, only one study used the KOOS [42] but did not show the benefits of an articulated valgus brace compared with a brace in a neutral position. In our sample, the efficacy of the brace seemed to wane with time, especially for everyday symptoms, which could have been due to a deterioration in the arthritis or to the less frequent use of the brace after one year, as shown by patient diaries, or perhaps premature wear of the unloader brace, which will have to be proven. Indeed, this type of custom-made device may need

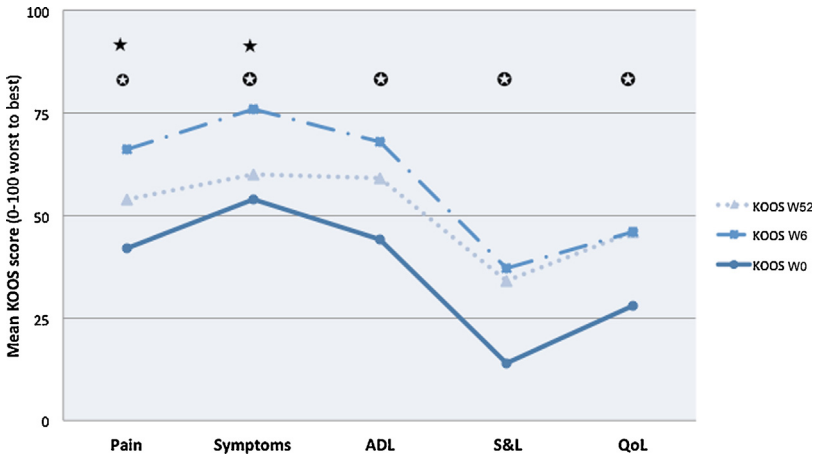


**Fig. 2.** Knee injury and Osteoarthritis Outcome Score (KOOS) profile for patients wearing the OdrA knee brace at inclusion (W0, $n = 20$) and week 6 (W6, $n = 19$) and week 52 (W52, $n = 18$). ADL: activities of daily living; SL: sports and leisure activities; QoL: quality of life. *$P < 0.05$ for W6 vs W0 and W52 vs W0. ✪ $P < 0.05$ for W6 vs W52.

**Table 3**
Spatio-temporal gait variables at inclusion (W0) and 6 weeks (W6) after wearing the OdrA knee brace and magnitude of the therapeutic effect (effect size).

| Gait variables | W0 $n=20$ | W6 $n=19$ | ES (95% CI) |
|---|---|---|---|
| Walking speed ($m.s^{-1}$) | $0.98 \pm 0.24$ | $1.08 \pm 0.26^*$ | 0.41 (0.06–0.75) |
| Stride length (m) | $1.08 \pm 0.20$ | $1.13 \pm 0.21^*$ | 0.25 (0.09–0.51) |
| Frequency ($cycle/min^{-1}$) | $53.4 \pm 6.6$ | $56.4 \pm 7.2^*$ | 0.45 (0.13–0.77) |
| Single-support time (% gait cycle) | $66.3 \pm 2.5$ | $65.9 \pm 2.7$ | 0.16 (0.12–0.20) |
| Double-support time (% gait cycle) | $15.3 \pm 2.5$ | $14.8 \pm 1.6$ | 0.20 (0.02–0.38) |
| Step dephasing (% gait cycle) | $51 \pm 0.6$ | $51.1 \pm 0.6$ | 0.16 (0.13–0.19) |
| Stride width (m) | $0.28 \pm 0.05$ | $0.29 \pm 0.06$ | 0.20 (0.08–0.32) |

Data are mean ± SD unless indicated.
ES, effect size; 95% CI, 95% confidence interval.
$^*P < 0.05$ comparing W6 and W0.

readjustments, particularly in cases of modified musculature of the patient (three patients in our series). Thus, to achieve its biomechanical effect properly, the custom-made brace must fit the contours of the limb perfectly.

Several studies have used the WOMAC (included in the KOOS) to assess the effect of a valgus knee brace. Most reported a significant improvement in symptoms, although with an ES < 0.8 in the most recent review of the literature [18]. Nonetheless, these data are difficult to compare because the populations were heterogeneous and the articulated braces did not all have the same degree of valgisation or the same unloader mechanism. For example, none used the dynamic external rotation effect of the OdrA system [24]. Therefore, the exact place of valgus braces and the characteristics of the population that could benefit from them have yet to be established in medial knee OA, despite the recent scientific interest in these devices [3,10]. We now need well-conducted studies with reference follow-up criteria, such as validated questionnaires [20] and/or the analysis of reference quantified gait parameters [43,44] in knee OA.

Most of our spatio-temporal gait variables showed significantly improvement but to a lower degree than for pain and function variables. This lower ES (0.16–0.45, depending on the variable) for objective criteria compared with subjective patient-reported outcomes may be explained in part by a greater inter-subject variability in these biomechanical criteria. The findings also raise the possibility of a placebo effect induced by wearing the brace. We found a fast (in six weeks) and significant increase (>10%) in speed, which corroborates certain results with other articulated knee braces, for example, for the absence of any effect on stride width [12,18]. Several hypotheses could explain this more efficient gait, the first being a postural gain due to the improved proprioception with the custom-made knee brace [11,45] but above all, the unloader effect on the medial compartment of the affected side, which is inversely associated with walking-related pain in knee OA [2,8,14,42].

Altogether, the new valgus brace with the OdrA system appears to have a benefit/risk ratio that is better than those reported so far with the reference unloader braces, or three-point braces. These results will be re-evaluated in the near future in a French multicentre randomized real-life study, conducted at the request of the French Health Authority, with both algo-functional and medico-economics criteria (cost-utility analysis). This study will allow for better determining the place of this new medical device in the therapeutic management of knee OA [5,10]. These preliminary results confirm the place of valgus braces in medial-compartment knee OA [46], as underlined by the new OARSI recommendations [4].

## Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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The PROTEOR group (France) provided the OdrA braces to Dijon CHU for this study and covered the costs of the orthotic specialist associated with moulding and correcting the braces. The PROTEOR group had no role in the study design, performance, writing of the manuscript and decision to publish.

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